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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/806,878	03/23/2004	Leon M. Clements	771CG.35249	2679
35979	7590	04/03/2009	EXAMINER	
BRACEWELL & GIULIANI LLP P.O. BOX 61389 HOUSTON, TX 77208-1389		PHONGSVIRAJATI, POONSIN		
		ART UNIT		PAPER NUMBER
		3686		
		NOTIFICATION DATE		DELIVERY MODE
		04/03/2009		ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docketing@bglp.com

Office Action Summary	Application No.	Applicant(s)
	10/806,878	CLEMENTS ET AL.
	Examiner	Art Unit
	SIND PHONGSVIRAJATI	3686

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 14 January 2009.
 2a) This action is **FINAL**. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-36 is/are pending in the application.
 4a) Of the above claim(s) none is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-36 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____. | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Claim Rejections - 35 USC § 112, First Paragraph

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claim 2 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 2 recites, "reviewing the electronic medical record for drug-drug interactions, duplicate therapies, and allergies", however, "duplicate therapies" was not found in the specifications by the Examiner.

Claim Rejections - 35 USC § 112, Second Paragraph

- The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1, 5, 7, 12, 16, 21, and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claims 1, 5, 7, 12, 16, 21, and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The statement "if the prescribed medication has been verified as suitable" in claim 1 does not limit the claim scope and makes optional but does not require steps to be performed. Similarly, claims 5, 7, 12, 16, 21, and 26 contain the same or similar optional language. Appropriate corrections are required.

Claim Rejections - 35 USC § 101

5. Claims 1-26 are rejected under 35 U.S.C. 101 as being directed towards non-statutory subject matter based on Supreme Court precedent, and recent Federal Circuit decisions, *In re Bilski U.S. Court of Appeals Federal Circuit 88 USPQ2d 1385*. The machine-or-transformation test is a two-branched inquiry; an applicant may show that a process claim satisfies § 101 either by showing that his claim is tied to a particular machine, or by showing that his claim transforms an article. See Benson, 409 U.S. at 70. Certain considerations are applicable to analysis under either branch. First, as illustrated by Benson and discussed below, the use of a specific machine or transformation of an article must impose meaningful limits on the claim's scope to impart patent-eligibility. See Benson, 409 U.S. at 71-72. Second, the involvement of the machine or transformation in the claimed process must not merely be insignificant extra-solution activity. See Flook, 437 U.S. at 590.

6. The methods recited in claims 1-26 are not tied to a machine nor transform the underlying subject matter to a different state or thing. See *Diamond v. Diehr*, 450 U.S. 175, 184 (1981); *Parker v. Flook*, 437 U.S. 584, 588 n.9 (1978); and *Gottschalk v. Benson*, 409 U.S. 63, 71 (1972).

7. Based on Supreme Court precedent, a method/process claim must (1) be tied to another statutory class of invention (such as a particular apparatus) (see at least *Diamond v. Diehr*, 450 U.S. 175, 184 (1981); *Parker v. Flook*, 437 U.S. 584, 588 n.9 (1978); *Gottschalk v. Benson*, 409 U.S. 63, 70 (1972); *Cochrane v. Deener*, 94 U.S. 780, 787-88 (1876)) or (2) transform underlying subject matter (such as an article or materials) to a different state or thing (see at least *Gottschalk v. Benson*, 409 U.S. 63, 71 (1972)).

8. A method/process claim that fails to meet one of the above requirements is not in compliance with the statutory requirements of 35 U.S.C. 101 for patent eligible subject matter. Here claims 1-26 fail to meet the above requirements because they are not tied to another statutory class of invention.

9. Nominal recitations of structure in an otherwise ineligible method fail to make the method a statutory process. See *Benson*, 409 U.S. at 71-72. As Comiskey recognized, "the mere use of the machine to collect data necessary for application of the mental process may not make the claim patentable subject matter." *Comiskey*, 499 F.3d at 1380 (citing *In re Grams*, 888 F.2d 835, 839-40 (Fed. Cir. 1989)). Incidental physical limitations, such as data gathering, field of use limitations, and post-solution activity are

not enough to convert an abstract idea into a statutory process. In other words, nominal or token recitations of structure in a method claim do not convert an otherwise ineligible claim into an eligible one.

10. The Applicant has clearly stated, "the Applicants' disclosure which teaches significant human involvement in the prescription order release process and in the documentation of medication dispensing, receipt, and consumption verification." The Examiner has concluded claims 1-26 are directed towards the pharmacist performing the claimed invention while using nominal recitations of a computer to provide post-solution activity.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

13. Claims 1-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chudy et al. (US 2004/0088187 A1) in view of the Department of Health ("A Pharmacy Service for Prisoners") in further view of Hingorane (US 7,278,028).

14. As to **Claim 1**, Chudy teaches a method for computerized monitoring of inventory of pharmaceuticals and dispensation of prescribed medication to patients in facilities in conjunction with computerized records including an electronic medical record stored in a computer having a computer memory and containing information about a patient to receive prescribed medication and the patient's medical history (Chudy, paragraphs 0023-0025, 0120, where the patient's medical history is inherent since the pharmacist must determine what prescription has been approved for fulfillment which requires a patient's medical history), the method comprising the steps of:

- α. reviewing the electronic medical record to verify that the prescribed medication is suitable for the patient (Chudy, paragraphs 0077-0079, 0082);
- β. authorizing release of the prescribed medication for the patient if the prescribed medication has been verified as suitable for the patient (Chudy, paragraphs 0123-0124);
- γ. labeling a unit packet of the prescribed medication for dispensing (Chudy, Fig. 6-7C);
- δ. delivering the unit packet of the prescribed medication to a facility unit that houses the patient (Chudy, paragraph 0145);

e. transferring the prescribed medication within the facility unit to administer the prescribed medication (Chudy, paragraph 0123);

But Chudy does not specifically disclose the computerized method being directed towards inmates or correctional facilities. The Department of Health does disclose using a pharmacy service for prisoners and sending prescription medication to correctional facilities (see at least sections 8-10).

It would have been obvious to one of ordinary skill in the art at the time of the invention to direct the invention of Chudy towards inmates in a prison, since inmates can be viewed as patients and the correctional facility can be viewed as a selected location the prescription medications must be delivered to. One would be motivated to provide inmates with pharmaceutical services since all prisoners should have appropriate access to a pharmacist or pharmacy staff (Department of Health, pg. 34).

The combination of Chudy and the DOH (Department of Health) does not specifically disclose forming a record in the computer of dispensing the unit packet of the prescribed medication to the inmate; forming a record in the computer indicating verification that the inmate received the unit packet of the prescribed medication; and forming a record in the computer verifying whether the inmate took the unit packet of the prescribed medication. Hingoranee does teach forming a record in the computer of dispensing the unit packet of the prescribed medication to the inmate (col. 8 lines 31-58); forming a record in the computer indicating verification that the inmate received the unit packet of the prescribed medication (Abstract, col. 8 lines 31-58); and forming a

record in the computer verifying whether the inmate took the unit packet of the prescribed medication (col. 8 lines 31-58).

It would have been obvious to one of ordinary skill in the art at the time of the invention to form a record in the computer indicating verification that the inmate received and took the prescribed medication. One would have been motivated to provide inmates with pharmaceutical services for the same motivation given above.

15. As to **Claim 2**, Chudy teaches the method of claim 1, wherein the step of reviewing the electronic medical record includes performing the step of automatically reviewing the electronic medical record for drug-drug interactions and allergies (Chudy, paragraph 0149). But Chudy does not specifically disclose reviewing the electronic medical record for duplicate therapies. However, the Examiner takes official notice that it is well known in the art to review an electronic medical record for duplicate therapies. It would have been obvious to one of ordinary skill in the art at the time of the invention to have reviewed an electronic medical record for duplicate therapies for the motivation for not providing a consumer with duplicate drugs.

16. As to **Claim 3**, Chudy teaches the method of claim 1, wherein the step of reviewing the electronic medical record includes performing the step of manually reviewing the electronic medical record prior to authorizing release of the prescribed medication (Chudy, paragraph 0082). But Chudy does not specifically disclose review laboratory results contained within the electronic medical record .However, the Examiner takes official notice that it is well known in the art to review laboratory results

contained within the electronic medical record. It would have been obvious to one of ordinary skill in the art at the time of the invention to have reviewed laboratory results within an electronic medical record for the motivation for avoiding any adverse prescription effects.

17. As to **Claim 4**, Chudy teaches the method of claim 1, further including the step of a pharmacist comparing the prescribed medication with a drug formulary of approved medication stored in the computer memory upon entry of a prescription into the computer (Chudy, paragraphs 0120-0121).

18. As to **Claim 5**, Chudy teaches the method of claim 4, further including the step of recommending a substitute medication if the step of comparing the prescribed medication with the drug formulary of approved medication indicates the prescribed medication is not contained with the drug formulary of approved medication prior to the step of authorizing release of the prescribed medication (Chudy, paragraphs 0117, 120-121, where recommending a substitute may be the prescribing physician's recommendation).

19. As to **Claim 6**, Chudy teaches the method of claim 1, further including the step of verifying that the patient is the patient who has been prescribed the prescribed medication prior to forming a record in the computer of dispensing the unit packet of the prescribed medication to the patient (Chudy, Fig. 28).

20. As to **Claim 7**, Chudy teaches the method of claim 1, further including the step of adding patient enrollment data records to the electronic medical record if information related to a new patient is not already present (Chudy, paragraph 0078).

21. As to **Claim 8**, Chudy teaches the method of claim 1, further including the step of sorting each of a plurality of unit packets into a shipment in accordance with a shipping schedule for delivery of the unit packets to each facility after the prescribed medication has been labeled (Chudy, Fig 7E and paragraph 90).

22. As to **Claim 9**, Chudy teaches the method of claim 1, further including the step of updating the inventory of pharmaceuticals at the facility in response to the step of delivering the unit packet of the prescribed medication to a facility unit (Chudy, paragraphs 0028- 0029, 0124-0132).

23. As to **Claim 10**, Chudy teaches the method of claim 8, further including the step of caching each electronic medical record on a pharmacy computer located remotely therefrom for each patient contained within each shipment scheduled to be shipped within a predefined time period prior to the step of reviewing the electronic medical record (Chudy, paragraphs 0029, where the caching of electronic medical records is inherent, since the method of Chudy uses a computer which comprises memory and a local storage (i.e. a hard drive) to cache data).

24. As to **Claim 11**, Chudy teaches the method of claim 8, further including the step of caching data related to each label to be printed for each of a plurality of shipments to a corresponding plurality of correctional facilities scheduled to be shipped within a

predefined time period prior to printing the respective label (Chudy, paragraphs 0030, where the caching of electronic medical records is inherent, since the method of Chudy uses a computer which comprises memory and a local storage (i.e. a hard drive) to cache data).

25. As to **Claim 12**, Chudy teaches the method of claim 1, wherein the step of forming a record in the computer verifying whether the patient took the unit packet of the prescribed medication indicates that the patient did not take the unit packet of prescribed medication and further includes the steps of:

- φ. subsequently locating the unit packet (Chudy, paragraphs 0033, 0090);
- γ. returning the unit packet of prescribed medication, if suitable for future use, to a central pharmacy for reclamation (Chudy, paragraphs 0117-0118, 0153); and
- η. adjusting the inventory of pharmaceuticals accordingly (Chudy, paragraphs 0124-0125).

26. As to **Claim 13**, Chudy teaches the method of claim 12, further including the step of adjusting the inventory of pharmaceuticals for patients in facilities following the step of delivering the unit packet of the prescribed medication to a facility unit that houses the patient (Chudy, paragraph 0125).

27. As to **Claim 14**, Chudy teaches the method of claim 1, further including the step of automatically refilling the prescribed medication for chronic conditions if the step of reviewing the computerized patient record and the electronic medical record to verify

that the prescribed medication is suitable for the patient has already been performed for the prescribed medication (Chudy, paragraph 0153, the Examiner takes the position that the automatic refilling comprises the computer having a record that the patient is permitted to refill a stated number of times and distributing the refill if allowed).

28. As to **Claim 15**, Chudy teaches the method of claim 1, further including the step of scheduling a time period in which the prescribed medication is to be dispensed to the patient (Chudy, paragraph 0149).

29. As to **Claims 16-36**, Claims 16-36 recites substantially similar limitations to claims 1-15, and are therefore rejected using the same art and rational set forth above.

Response to Arguments

In regards to the 112(2) rejection, Examiner thanks Applicant for the correction and will remove the 112(2) rejection in regards to lack of antecedent basis.

As to Applicant's argument towards no prima facie case of obviousness, the Examiner respectfully disagrees. First, Applicant states that, "Applicants respectfully submit that there would be no motivation to combine references trader either rationale (A)-(F)", however, under KSR, no motivation is required to combine references under rational (A)-(F). Examiner has clearly used rationale (G) and has referenced the motivation used the applied references. Second, Applicant argues that neither of the references recognizes the problem or the source of the problem and for this reason, Chudy teaches away from the claimed invention. This argument is moot because patent

examiners are not required to recognize the same problem or the source of the problem for determining obviousness under 35 U.S.C 103. The Supreme Court in KSR reaffirmed the familiar framework for determining obviousness as set forth in Graham v. John Deere Co. (383 U.S. 1, 148 USPQ 459 (1966)), but stated that the Federal Circuit had erred by applying the teaching- suggestion-motivation (TSM) test in an overly rigid and formalistic way. KSR, 550 U.S. at ___, 82 USPQ2d at 1391. Specifically, the Supreme Court stated that the Federal Circuit **had erred in four ways:** (1) “**by holding that courts and patent examiners should look only to the problem the patentee was trying to solve ” (Id. at ___, 82 USPQ2d at 1397);** (2) **by assuming “that a person of ordinary skill attempting to solve a problem will be led only to those elements of prior art designed to solve the same problem” (Id.)** (emphasis added); (3) by concluding “that a patent claim cannot be proved obvious merely by showing that the combination of elements was obvious to try” (Id.); and (4) by overemphasizing “the risk of courts and patent examiners falling prey to hindsight bias” and as a result applying “[r]igid preventative rules that deny factfinders recourse to common sense” (Id.). However, the disclosure from the Department of Health specifically teaches of a need for a pharmacy service system for prisoners.

Furthermore, the computerized monitoring of inventory of pharmaceuticals for inmates is merely the intended use of the claimed invention. For example, limitation from claim 1 recites, “reviewing the electronic medical record to verify that the prescribed medication is suitable **for the inmate;** authorizing release of the prescribed

medication for the inmate if the prescribed medication has been verified as suitable **for the inmate**; labeling a unit packet of the prescribed medication **for dispensing to the inmate**;" (emphasis added). Recitations of intended use are not given patentable weight (MPEP 2106(II)(C)). If Applicant intended the claimed invention to be limited to inmates in correctional facilities, the Examiner recommends that the limitations should be rewritten to more positively recite the monitoring and dispensation of prescribed medications to the inmates. Examiner will rewrite the limitations as an example, -- reviewing the inmate's electronic medical record to verify that the prescribed medication is suitable; authorizing release of the inmate's prescribed medication if the prescribed medication has been verified; labeling a unit packet and dispensing the inmate's prescribed medication--. Applicant's second argument is directed towards Chudy teaching away from the claimed invention. However, a reference will teach away if it suggests that the line of development flowing from the reference's disclosures is unlikely to be productive of the result sought by the Applicant (*In re Gurley*, 31 USPQ2d 1130 (Fed. Cir. 1994)). Applicant states that the claimed invention requires human interaction, however, no where in the limitations, claims 1 for example, requires that the pharmacist or any other human perform any tasks. The Examiner interprets that the Applicant has imported limitations from the specifications into the claim. Applicant's second argument is directed towards no reasonable expectation of success, however, Applicant's arguments are again directed towards the intended use of the claimed invention.

As to Applicant's argument toward Chudy not teaching of verifying the suitability of the prescribe medication, the Examiner cannot analogize Applicant's example referring to the movie, "It's a Wonderful Life", since the Examiner has not seen said movie but more importantly the transcript for said movie has not been provided in the IDS. However, Applicant's arguments interpret that the fulfillment and verification of the prescription order is the same thing. No where in the disclosure of Chudy does Chudy define verification as being defined as determining that the correct medication is in each medication. Checking to ensure that the correct medication is in each container may be an essential step in the verification process but not the entire verification process.

Applicant's arguments with respect to claims 1-36 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

30. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SIND PHONGSVIRAJATI whose telephone number is (571) 270-5398. The examiner can normally be reached on Monday - Thursday 8:00am-5:00pm (ET).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jerry O'Connor can be reached on (571) 272-6787. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or (571) 272-1000.

/S. P./
Examiner, Art Unit 3686
27 March 2009

/Gerald J. O'Connor/
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